

CHARGE: 501(c)—the strength of the *thyroid-digitalis tablets* differed from that which they were represented to possess; and 502(a)—the statement "Each tablet contains: Thyroid 5 grains" on the label of the *thyroid tablets* was false and misleading.

The information alleged also that a number of food supplement tablets were adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

PLEA: Nolo contendere.

DISPOSITION: 6-13-60. \$750 fine.

6210. Syngesterone (progesterone). (F.D.C. No. 44562. S. Nos. 98-803 P, 996 R, 1-662 R.)

QUANTITY: 350 individually cartoned 10-cc. vials at Chamblee, Ga.

SHIPPED: 12-14-59, from Brooklyn, N.Y., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Ctn. and vial) "Syngesterone Brand of Progesterone, U.S.P. in aqueous suspension 25 mg./cc. For Intramuscular Use Only * * * Chas. Pfizer & Co., Inc., New York, New York."

ACCOMPANYING LABELING: Leaflet in carton entitled "Syngesterone Brand of Progesterone U.S.P."

RESULTS OF INVESTIGATION: Examination showed that the article contained from 69.7 percent to 124.1 percent of the labeled amount of *progesterone*. The United States Pharmacopeia requires that sterile progesterone suspension contain not less than 93 percent and not more than 107 percent of the labeled amount of *progesterone*.

LIBELED: 5-4-60, N. Dist. Ga.

CHARGE: 501(b)—when shipped, the strength of the article differed from and its quality fell below the standard for "Sterile Progesterone Suspension" set forth in the United States Pharmacopeia; and 502(a)—the name "Syngesterone Brand of Progesterone, U.S.P. in Aqueous Suspension 25 mg./cc." was false and misleading.

DISPOSITION: 6-14-60. Default—destruction.

6211. Vitamin B₁₂ injection. (F.D.C. No. 44452. S. No. 27-713 R.)

QUANTITY: 6 10-cc. vials at Davenport, Iowa.

SHIPPED: 3-22-60, from Minneapolis, Minn.

LIBELED: 5-11-60, S. Dist. Iowa.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each cc. contains: Vitamin B₁₂ activity * * * equivalent to: Cyanocobalamin 10 Mcg * * * Fortified with vit. B₁₂ cryst 100 mcg" was false and misleading as applied to the article which contained less than 50 percent of the declared amount of vitamin B₁₂.

DISPOSITION: 5-27-60. Consent—destruction.

DRUG FOR VETERINARY USE

6212. Egg ration. (F.D.C. No. 44575. S. Nos. 7-045/6 R.)

QUANTITY: 22 100-lb. bags and 6 100-lb. bags at Fairfield, Vt.

SHIPPED: Some time within the 6 months period prior to 5-6-60, from Oneonta, N.Y., by Elmore Milling Co., Inc.

LABEL IN PART: (Bags) "Elmore Complete Market Egg Ration (1A) * * * Arsanilic Acid—0.01% * * * Manufactured by Elmore Milling Company, Inc." and "Elmore Complete Market Egg Ration (1A) * * * 3-Nitro-4 Hydroxyphenylarsonic Acid—0.005% * * * Manufactured by Elmore Milling Company, Inc., Oneonta, New York."

LIBELED: 5-14-60, Dist. Vt.

CHARGE: 501(c)—when shipped, the strength of the article differed from and its quality fell below that which it purported and was represented to possess since the 22-bag lot contained less than the declared amount of arsanilic acid, and the 6-bag lot contained less than the declared amount of 3-nitro-4 hydroxyphenylarsonic acid.

The libel alleged also that another article known as "Hog Ration" was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 6-3-60. Consent—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6213. Tranquilease (cosmetic cream). (F.D.C. No. 41505. S. No. 4-382 P.)

QUANTITY: 48 individually cartoned jars at Washington, D.C.

SHIPPED: 1-20-58, from Philadelphia, Pa., by Denney & Denney, Inc.

LABEL IN PART: (Jar) "TRANQUILEASE - FRANCES DENNEY The Original Cosmetic Tranquilizer for the Skin * * * 1.8 Oz. Net."

ACCOMPANYING LABELING: Carton inserts entitled "Tranquilease The only cosmetic of its kind" and leaflets entitled "Bulletin from Frances Denney."

RESULTS OF INVESTIGATION: Analysis showed that the article was a white, perfumed oil-in-water cream emulsion containing glycerol monostearate, waxes (including lanolin and/or sterols), inorganic pigments (mostly zinc oxide and titanium dioxide), mineral oil, glycerol, and a nitrogen compound (probably an amide).

LIBELED: 4-4-58, Dist. Columbia.

CHARGE: 502(a)—when shipped, the labeling and the name of the article contained false and misleading representations that the article would tranquilize the skin and correct all abnormal skin conditions resulting from emotional upsets, tension, and fatigue.

The libel alleged also that the article was misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics.

DISPOSITION: On 5-15-58, Frances Denney and Denney & Denney, Inc., appeared as claimants and denied that the article was a drug or that it was misbranded. Thereafter, the Government and the claimants filed written interrogatories. The claimants objected in part to the Government's interrogatories for specific reasons, and a further general objection was made to all the interrogatories on the grounds of self-incrimination. On 11-14-58, the court entered the following memorandum opinion, ruling against the claimants on their self-incrimination objection, and ruling in part for the claimants and in part for the Government on the other objections (23 F.R.D. 192):

*See also Nos. 6203, 6205, 6207-6211.